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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,718	04/04/2000	HONG YU	6687.US.01	5110

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VYSIS, INC  
PATENT DEPARTMENT  
1300 E TOUHY AVENUE  
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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/542,718

Applicant(s)

YU ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **FINAL ACTION**

1. This action is in response to the Amendment and Terminal Disclaimer filed 22 November 2005, and to the complying complete set of claims filed 08 March 2006. Claims 1-5 have been amended and are now under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, second paragraph***

3. In view of Applicants' amendment of claim 3 such that the claim now recite "the target sequence" in step (a), the rejection of the claim under 35 USC 112, second paragraph set forth in the prior Office action is withdrawn.
4. In view of Applicants' amendment of claim 1 to recite a "combination of nucleic acids" comprising first and second nucleic acids, the rejection of claims 1 and 3-4 under 35 USC 112, second paragraph set forth in the prior Office action is withdrawn.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY  
APPLICANTS' AMENDMENTS:**

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6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants' specification discloses primers SEQ ID NO: 2 and SEQ ID NO: 3 and probes SEQ ID NO: 4 and SEQ ID NO: 5, as well as probe sequences "having" SEQ. ID. Nos. 4 and 5 (see pages 2, 4-5 and 8-9). However, Applicants' claims as amended encompass primers "having" any "nucleotide sequence of" SEQ ID NO: 2 or SEQ ID NO: 3 (as opposed to primers that consist of the specific sequences set forth in SEQ ID Nos 2 and 3), as well as probes having any "nucleotide sequence of" SEQ ID NO: 4 or 5 (rather than probes having/comprising the complete sequences of SEQ ID Nos 4 or 5). The originally filed specification does not provide basis for the additional molecules that are encompassed by Applicants' claims as amended. (It is also noted that while the response at page 5 states where basis for nucleic acid "combinations" may be found in the specification, the response does not indicate where in the specification support may be found for the broader genus of molecules now encompassed by Applicants' claims.) Accordingly, Applicants' amendment introduces new matter.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY**

**APPLICANTS' AMENDMENTS:**

8. Claims 1- 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Drazen et al (WO 98/39477 [9/1998]).

It is noted that the claims have been amended such that they now recite the language "having a nucleotide sequence of SEQ ID NO:\_\_\_\_", such that the claims are sufficiently broad so as to encompass any molecule comprising any subsequence of the recited SEQ ID Nos.

With regard to claims 1-2 and 5, Drazen et al disclose kits comprising primer pairs that specifically amplify 2 different codon 16 variants of the beta2-adrenergic receptor gene, as well as control DNA molecules including both variant receptor gene alleles (see entire reference, particularly page 28). The kits of Drazen et al are sufficient to meet the requirements of claims 1-2 and 5 as now written, and therefore Drazen et al anticipates claims 1-2 and 5.

With regard to claims 3-4, Drazen et al disclose allele-specific amplification of a portion of a beta2-adrenergic receptor target gene (see entire reference, particularly, e.g., pages 2-4, Examples 2-3). With further regard to claim 4, Drazen et al further disclose amplification of a portion of the beta2-adrenergic receptor gene, followed by allele-specific hybridization to effect detection of a target allele (see, e.g., pages 26-27). As the primers employed by Drazen et al are sufficient to meet the requirements of the claims as now written, Drazen et al also anticipate claims 3-4.

***Claim Rejections - 35 USC § 103***

9. Claims 1-5 are rejected under 35 USC 103(a) as being unpatentable over Dewar et al in view of Drazen et al and Matalon et al, for reasons set forth in the Office actions of October 11, 2000 and August 25, 2005.

The response traverses the rejection on the following grounds. First, the response argues that the Matalon et al reference does not “disclose or teach anything regarding the human beta2-adrenergic receptor gene,” that Matalon et al do not “teach or provide any ‘unexpected’ results for their claimed primers and probes,” and that Matalon et al “is incorrect in stating that the design and selection of suitable probes and primers is routine.” Next, Applicants’ urge that many primers and probes that are initially selected in use for PCR/hybridization may fail to function as desired, and provide a variety of reasons why “all possible primer and probe sequences are not functionally equivalent and a commercially acceptable efficiency of any primer or probe sequences cannot be predicted with any certainty.” Finally, Applicants’ cite a reference, He et al, and assert that the reference “details the unexplained difficulties surrounding the selection of primer and probe sequences,” and “suggests choosing different primer or probe sequences instead of trying to get an unresponsive set of primers to work by changing reaction conditions.”

These arguments have been thoroughly considered, but are not persuasive. First, with regard to the Matalon et al reference, the reference was cited only for its teachings with regard to the routine nature of selecting and producing suitable probes and primers for use in PCR and allele specific hybridization (see Office action of

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October 11, 2000, pages 5-6). The examiner did not rely on any teachings contained in Matalon et al with regard to the beta2-adrenergic receptor gene, and the response does not address the teachings of Dewar et al and Drazen et al, on which the examiner did rely (other than in restating the examiner's arguments regarding those references). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the primers and probes of Matalon et al, and the types of results (be they unexpected or otherwise) obtained by Matalon et al with those primers and probes have no bearing on the patentability of Applicants' claims. With regard to applicants' arguments pertaining to the He et al reference, and possible difficulties one may encounter in attempting to use various primers and probes in amplification and hybridization, it is noted that Applicants' claims are no longer limited to the specific primers and probes exemplified in the specification, but are rather sufficiently broad so as to encompass a wide variety of primers and probes (see discussion above). Thus, the features upon which Applicants' rely (i.e., the particular primers of SEQ ID NOS 2-3 and probes of SEQ ID Nos 4-5, and the fact that these molecules have been shown to function in the assays described in the specification) are not required by the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As an ordinary artisan could clearly select primers and probes encompassed by the claims that would function in amplification and detection of

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beta2-adrenergic receptor gene sequences, Applicants' arguments are not persuasive with regard to the invention claimed.

The combined references of Dewar et al, Drazen et al and Matalon et al suggest all the limitations of present claims 1-5, and therefore this rejection is maintained.

***Terminal Disclaimer***

10. The terminal disclaimer filed on 22 November 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,593,092 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

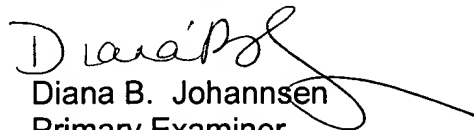
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Diana B. Johannsen  
Primary Examiner  
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